



**AESCULAP®**

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**510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990**

**Aesculap Modular Monopolar Electrodes**

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**Submitted by:** Aesculap®, Inc.  
1000 Gateway Blvd.  
So. San Francisco, CA 94080  
**Contact:** Mary Ellen Holden  
**Phone:** (415) 876-7000 x348  
**FAX:** (415) 589-3007

**Product:** Aesculap Modular Monopolar Electrodes

**Common Name:** Monopolar Electrodes

**Intended Use**

The Modular Monopolar Electrodes presented in this submission are intended for use in endoscopic surgery (laparoscopy, thoracoscopy) for coagulation and dissection of selected tissue.

**Technological Characteristics**

Aesculap currently markets a line of non-modular endoscopic monopolar electrodes and a line of modular endoscopic monopolar scissors and forceps which are subject to 510(k) clearance. This submission represents the following design changes:

- Change electrodes from a non-modular design to a modular design.
- Change in tip insulation material.
- Change in shaft insulation material.

The Modular Monopolar Electrodes are made up of 3 separate components: an insulated handle (GK382R), an insulated shaft (GK380R) and a working tip. The working tips come in several different styles (i.e. J-shaped hook electrode GK383R) which can be used interchangeably. All components are reusable and disassemble for cleaning and sterilization.

The assembled electrodes are 5 mm in diameter and 450 mm in length. They have no suction/irrigation feature.

**Performance Standards**

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's Modular Monopolar Electrodes comply with the requirements of IEC 601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment.)

The Modular Monopolar Electrodes will be manufactured in accordance with ISO and German Din Standards. Furthermore, Aesculap AG has received ISO 9001 certification.

**Sterilization**

The Modular Monopolar Electrodes are provided non-sterile and must be sterilized prior to use. The devices may be sterilized by steam sterilization.

**Substantial Equivalence**

Aesculap's Modular Monopolar Electrodes shares similar features and function with corresponding devices distributed by Aesculap, Brimfield and Marlow.